MYLAN PHARMACEUTICALS INC
781 Chestnut Ridge Road • P. O. Box 4310 • Morgantown, West Virginia 26504-4310 U.S.A. • (304) 599-2595

March 16, 1999

Dockets Management Branch (HFA-305)
FOOD & DRUG ADMINISTRATION
5630 Fishers Lane, Room 1061
Rockville, MD 20852

RE: Draft Guidance for Industry: *Placing the Therapeutic Equivalence Code on Prescription Drug Labels and Labeling*: [Docket No. 98D-1266]

Dear Sir/Madame:

The January 28, 1999, *Federal Register* (Vol. 64, No. 18, pp. 4434 - 4435) contained an announcement regarding the availability of the referenced draft guidance and a request for comments and suggestions on this document. The guidance was assigned Docket Number 98D-1266.

The intent of the draft guidance, as noted in the guidance introduction, is to clarify the Agency's position regarding the placement of the therapeutic equivalence code on approved FDA drug product labels and labeling.

Mylan has reviewed the referenced draft guidance and has the following general comments:

- Mylan agrees with the guidance and supports the concepts set forth therein.

- Mylan believes that the placement of the therapeutic equivalence code on the label will enhance both patient protection and safety. The potential for a pharmacist to incorrectly fill a prescription with the wrong generic version is substantial when two reference listed drug products have the same established name and strength but are not bioequivalent to each other. In fact, these two reference listed drug products may have different dosage and administration instructions. Since the label of a generic product currently provides only the established name, strength and in some instances the daily dose of the product, it is difficult for the pharmacist to determine which reference listed drug product the generic product has established bioequivalence. Product labels that bear the therapeutic equivalence code will reduce the risk of this type of dispensing error.

  Mylan has received many calls and inquiries from health care professionals who have expressed concern and/or confusion regarding the dispensing of Mylan products that are generic versions of multiple-source reference listed products, i.e., diltiazem, nitroglycerin transdermal systems. The placement of the therapeutic equivalence code on the product labeling will eliminate this confusion and assist the health care professional in selecting the appropriate generic product.

98D-1266

C2

Department—Fax Numbers		Information Systems	(304) 285-6404	Purchasing	(304) 598-5401
Accounting	(304) 285-6403	Label Control	(800) 848-0463	Quality Control	(304) 598-5407
Administration	(304) 599-7284	Legal Services	(304) 598-5408	Research & Development	(304) 285-6409
Business Development	(304) 599-7284	Maintenance & Engineering	(304) 598-5411	Sales & Marketing	(304) 598-3232
Human Resources	(304) 598-5406	Medical Unit	(304) 598-5445		

- Mylan requests that the guidance be revised to change the recommended language from "AB to CHICOSE®*" to "AB-rated to CHICOSE®*". It has been Mylan's experience that the term "AB-rated" is more meaningful to health care professionals than the term "AB". Therefore we are requesting that the guidance be revised to permit the use of "AB-rated" on the labeling.

- Finally, Mylan is requesting clarification on the acceptable location of the disclaimer identifying the owner of the trademark. May the disclaimer appear on a different label panel than the therapeutic equivalence code, i.e., the therapeutic equivalence code, "AB to CHICOSE®*", on the center panel and the disclaimer, "* CHICOSE® is a registered trademark of Marx Brothers, Inc.", on the side panel?

In conclusion, Mylan wishes to express our support for the draft guidance entitled "Placing the Therapeutic Equivalence Code on Prescription Drug Labels and Labeling". Furthermore, Mylan agrees that the placement of therapeutic codes on labels promotes the safe and accurate dispensing of drug products.

Should you have any questions regarding these suggestions, please contact the undersigned at (304) 599-2595, extension 6600 or via facsimile at (304) 285-6407.

Sincerely,

Frank R. Sisto
Vice President
Regulatory Affairs

FRS/cmm

FRANK SISTO
MYLAN PHARMACEUTICALS INC
3711 COLLINS FERRY RD DOCK 11
MORGANTOWN WV 265052356
(304)599-2595

SHIP DATE: 16MAR99
ACCOUNT # 112763546
MAN-WGT:1 LBS

( ) -

TO: Dockets MGMT BRANCH
FDA
5630 Fisher Lane
Room 1061
Rockville MD 20852

243 0995 445

FedEx. POWERSHIP 3

REF: 314

PRIORITY OVERNIGHT WED
AA

CAD # 648199 16MAR99

FedEx Letter

Trk# 243 0995 445

153077-077 RIT 9/98

IAD

20852-MD-US ZM EDG

World On Time®